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10/530,171	05/17/2005	Youko Hirakawa	235054	9015
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,171	Applicant(s) HIRAKAWA ET AL.
	Examiner LYNN BRISTOL	Art Unit 1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11/30/07 and 2/29/08.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3,4 and 12-41 is/are pending in the application.
 4a) Of the above claim(s) 12-35 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3,4 and 36-41 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/07 and 2/29/08 has been entered.
2. Claims 1, 3, 4 and 12-41 are all the pending claims for this application.
3. The amendment of Claims 36-38 to depend from pending examined Claim 3 and the amendment of Claims 39-41 to depend from pending examined Claim 4 in the Response of 11/30/07 is acknowledged. Accordingly, the restriction of Claims 36-41 is withdrawn.
4. Claims 12-35 are withdrawn.
5. Claims 1, 3, 4 and 36-41 are all the pending claims under examination.
Applicants' amendments to the claims have necessitated new grounds for rejection.

Supplemental ADS Submission

6. The supplemental ADS filed on 11/30/07 to correct the spelling of the inventor name Yoko Hirakawa (MPEP 601.05), has been entered.

Applicants' comments on p. 7 of the Response of 11/30/07 are acknowledged.

Withdrawal of Rejections

Claims - 35 USC § 112, second paragraph

7. The rejection of Claims 1, 3 and 4 as being indefinite for the recitation "a cell positioned at the formation of a solid tumor" is withdrawn in view of the amendment of the claims to delete the phrase from claim 1.

Rejections Maintained

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description (1)

8. The rejection Claims 1, 3 and 4 (and Claims 36-41) under 35 U.S.C. 112, first paragraph, in lacking written support for any kind of cultured breast cancer cell and the solid tumor from which it is formed, and which cells express a part of the antigen on the cell surface and which comprises residues 600-1,960 of SEQ ID NO: 17 is maintained.

The claims have been amended to recite that the antigen consists of a portion that is cell-surface exposed, also comprises residues 600-1,960 of SEQ ID NO:17 and is expressed on a cell from a solid tumor formed by cultured gastric, breast, colon and/or esophageal cancer cells upon subcutaneous transplantation.

a) The amendment of the claims, Applicants allegations in the Response of 11/30/07 and the 1.132 Declaration of Dr. Hirakawa have been carefully considered and

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are not found persuasive. Applicants have not provided sufficient support for "a cultured cancer cell from breast cancer" in the original specification or with sufficient evidence in the 1.132 Declaration.

The following cultured cancer cells are shown in the original specification to demonstrate cell surface expression of nmMHC-A (SEQ ID NO: 17) when transplanted s.c. into a mouse:

Example 1: MKN45 *gastric* cancer cell line;

Example 2: recombinant nmMHC-A-expressing cell lines, designated FL1, FL2 and FL7, and derived from HCT-15 (human *colon* cancer cell line); and

Example 4: human *colon* cancer (Caco-2, DLD-1, SW620, WiDr-Tc, SW837), human *esophageal* cancer (TE-8), human *gastric* cancer (HSC-3, MKN-1, MKN45, B37).

The Declaration evidence demonstrates that the GAH antibody stains MKN45 *gastric* cancer cells after s.c. transplantation (Figure A). The Declaration evidence demonstrates that the GAH antibody and anti-nmMHCA peptide (SEQ ID NO: 22) antibody immunostain colon, esophageal and breast cancer cells although none of the actual cell lines for the respective categories of cancer are disclosed in the Declaration (Figure B and C). Are these the same tumor cell lines or different from those disclosed in the specification? Applicants provide a single example of an immunostained breast cancer tissue sample (Figure C) without so much as identifying what breast cancer cell line was used in the experiment. Chiavegato et al. (*Virchows Archiv.* 426:77-86 (1995); cited in the PTO from 892 of 1/11/07) recognized human mammary epithelial cells and

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myofibroblasts expressing nmMHCA during different phases of neoplasia in tissue sections.

Thus while the applicants have demonstrated the antigen meeting the requirements of the claims for a reasonable number of gastric, colon and/or esophageal cultured cancer cell lines, they have not demonstrated that just *any* cultured breast cancer cell meets all of the claim limitations. Applicants have not shown by a preponderance of the evidence that the nmMHCA antigen is a tumor marker for just any breast cancer cell line or any solid breast tumor.

b) In the Office Action of 8/31/07, the Examiner stated:

"Wei et al. (Molec. Biol. Cell 11:3617-3627 (2000)) disclose a truncated nmMHC-A comprising residues 593-1961 and compare the intracellular localization of the protein with the full length protein in transfected HeLa cells. Wei teaches that the truncated protein has lost the ability to bind actin, but otherwise retains the property of filament assembly and the ability to be incorporated into endogenous myosin. In other words, the truncated protein is never shown to become associated with the cell membrane where it is exposed on the surface. Wei does not support truncated forms of nmMHC-A occurring on the surface of the HeLa cancer cell line. Wei teaches that despite the abnormal, rounded morphology of cells transfected with truncated nmMHC-A, the HeLa cells are capable of undergoing cytokinesis."

On p. 9 of the Response of 11/30/07, Applicants allege that in amending the claims to recite that the antigen is surface exposed and comprises residues 600-1,960 of SEQ ID NO: 17, that the rejection is overcome in view of Wei's truncated nmMHCA ($\Delta N592$).

This aspect of the response is found persuasive, and therefore this aspect of the rejection is withdrawn.

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 3, 4 and 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1, 3, 4 and 36-41 are indefinite for the recitation "exposed on a surface of a cell of a solid tumor" because it is not clear what cell of the solid tumor is expressing the antigen. Would every *tumor* cell in the solid tumor mass express the antigen on its surface? Could other cells which are part of the solid tumor mass such as epithelial cells associated with the vasculature or stromal cells lining the tumor also express the antigen? For example, Chiavegato et al. (Virchows Archiv. 426:77-86 (1995); cited in the PTO from 892 of 1/11/07) teaches that "stromal cells were always stained by all anti-nmMyHC antibodies (p. 84, Col. 1, ¶1). If a solid tumor does comprise tumor- and non-tumor cell types, it is not clear which of the heterogeneous population of cells in a solid tumor are expressing the antigen when referring to "a cell".

Applicants' allegations starting on the bottom of p. 7 to p. 8 of the Response of 11/30/07 and the 1.132 Declaration stating that "every cell of the solid tumor mass would express part of the non-muscle myosin heavy chain (nmMHC-A) antigen (SEQ ID NO:17) on its cell surface" is not read into the claims. Further, it is understood from the

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Declaration evidence that only all populations of the MKN45 gastric tumor cells would be reactive with the GAH antibody (legend to Figure A).

b) Claims 3, 4 and 36-41 are indefinite for the recitation "a cultured cancer cell" in Claims 3 and 4 because the recitation is a broadening limitation and therefore encompasses a broader genus of cultured cancer cells compared to the species of cultured cancer cells set forth in the Markush group of Claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor or carrying out his invention.

Written Description (2)

10. Claims 1, 3, 4 and 36-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass a genus of tumor antigens that are not described in the specification and that Applicants were not in possession of at the time of filing.

Claims 1, 3, 4 and 36-41 are interpreted as being drawn to any tumor marker antigen having a cell-surface exposed portion on a cell from a gastric, breast, colon or esophageal solid tumor and further comprising amino acid residues 600-1,960 of SEQ

ID NO:17. The claims encompass any antigen having any amino acid composition from residues 1-599 and amino acid residues 600-1,960 of the nmMHCA protein.

The specification discloses the GAH antibody being reactive with a 200 Kd protein having the full length sequence of SEQ ID NO: 17 and identified as human non-muscular myosin A chain (nmMHCA) (Example 1). The specification discloses three polyclonal anti-nmMHCA antibodies generated to peptides of SEQ ID NOS: 20, 21 or 22, where each peptide corresponds to a region "locally present on the cell surface" (p. 24, lines 9-14) and were expression was demonstrated on the MKN45 gastric cancer tumor (Example 3). The specification does not disclose any other protein recognized by the GAH antibody or the polyclonal antibodies and meeting the structural and functional criteria for the antigen of the instant claims. The specification does not provide sufficient written description as to the structural features of the claimed genus of antigens and the correlation between the chemical structure and function of the genus, such as structural domains or motifs that are essential and distinguish members of the genus from those excluded. The specification does not disclose a single species with less than 100% sequence identity to the nmMHCA protein of SEQ ID NO:17. Thus one of skill in the art would reasonably conclude that Applicants were not in possession of any other tumor marker protein than the nmMHCA protein of SEQ ID NO:17.

A "representative number of species" means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species

encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]. " See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)(Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.).

Therefore, only an isolated nmMHCA antigen comprising SEQ ID NO:17, but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph.

Written Description (3)

11. Claims 36-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass ranges for tumor antigen production or expression that are not described in the specification and that Applicants were not in possession of at the time of filing.

a) Claims 36-38 are interpreted as being drawn to the antigen of Claim 3 which is produced in a greater amount by a cell of the solid tumor formed by subcutaneous transplantation of the cultured gastric, breast, colon and/or esophageal cancer cell than by any one of the cultured cancer cells, where production by the cell of the solid tumor is "at least 3 times greater" (Claim 36), or "at least 4 times greater" (Claim 37) or "at least 10 times greater" (Claim 38), than the amount produced by the cultured cell.

The claims encompass ranges for the production of the antigen in a cell from a solid tumor formed from the transplanted cancer cells that are either a) not supported by the original disclosure for each of the 4 different cancer cell types or b) not supported by the original disclosure for the range per se.

b) Claims 39-41 are interpreted as being drawn to the antigen of Claim 4 which is present in a greater amount on the surface of a cell of the solid tumor formed by subcutaneous transplantation of the cultured gastric, breast, colon and/or esophageal cancer cell than on the surface of any one of the cultured cancer cells, where the amount of the antigen on the surface of the cell of the solid tumor is "at least 3 times

greater" (Claim 39), or "at least 4 times greater" (Claim 40) or "at least 10 times greater" (Claim 41), than the amount of the antigen on the surface of the cultured cell.

The claims encompass ranges for the surface-expressed amount of the antigen on a cell of a solid tumor formed from the transplanted cancer cells that are either a) not supported by the original disclosure for each of the 4 different cancer cell types or b) not supported by the original disclosure for the range per se.

The specification discloses "examples of the increase of the present invention include increase by 3 times or more,...4 times or more, and...10 times or more" (p. 7, lines 18-20); "The GAH antibody showed a higher reactivity of about 18 times for the tumor cells than the cultured cells of MKN45" (p. 14, lines 25-26); When the increasing degree or reaction by each antibody in the tumor cell formed by the transplantation of MKN45, in comparison with the MKN45 cultured cells, was calculated by subtracting the reaction of normal rabbit immunoglobulin for control as a background value, 3 times or more of increase was found by the antibody A (nmMHCA peptide of SEQ ID NO: 20) and B (nmMHCA peptide of SEQ ID NO: 21), and 10 time or more of increase by the antibody C (nmMHCA peptide of SEQ ID NO:22). It was found that the existing amounts of the partial sequences represented by SEQ ID NOS: 20, 21 and 22 are increased in the tumor cells formed by transplantation of MKN45 in comparison with the MKN45 cultured cells (p. 24, lines 4-14); and in Example 4 Applicants compare 10 different cells lines and for each line given to what appears to be a single mouse, they compare antigen amount per cell to tumor growth inhibition. It is not possible to interpret from the

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text in the specification or the data in Figure 6, what increase occurs with s.c. transplantation.

The specification does not show that the overall production of or the cell surface-expressed form of the nmMHCA antigen much less the extracellular domains corresponding to the sequences of SEQ ID NOS: 20, 21 or 22, are changed between a cultured cell and a s.c. transplanted cell for anything but the MKN45 human gastric tumor cell line. Applicants have provided no evidence in the originally filed specification and no additional evidence in the 1.132 Declaration to support the number and different kinds of cancers that are presently encompassed by the claims as having increased production and/or increased cell-surfaced expressed amounts for the antigen over a corresponding cultured cell type.

The specification provides very general literal support for the claimed ranges corresponding to any tumor culture cell. However, a review of the actual data does not reveal that all the tumor cell types encompassed by the claims, would in fact have production levels falling within the ranges of Claims 36-38 or cell-surface expressed amounts falling within the ranges of Claims 39-41.

First, the ranges for all of the claims have a lower limit but are indefinite for the upper limit. In other words, there is no upper limit for antigen expression, and this is not supported by the specification.

Second, it is with only the MNK45 human gastric cancer cell/tumor that Applicants have actually made any attempt to make comparative nmMHCA antigen expression. Applicants states "The GAH antibody showed a higher reactivity of about 18

times for the tumor cells than the cultured cells of MKN45" (p. 14, lines 25-26), but it is not clear if this level represent production or cell-surface expression. Since the GAH antibody is surface reactive, presumably, this reflects the increased amount on the cell surface. However, when Applicants compare the three rabbit polyclonal antibodies directed against the three surface-exposed epitopes for nmMHCA on the MKN45 tumor, they observe 3 times or more of increase using the antibody A (nmMHCA peptide of SEQ ID NO: 20) and B (nmMHCA peptide of SEQ ID NO: 21), and 10 times or more of increase with the antibody C (nmMHCA peptide of SEQ ID NO:22). Thus depending on which antibody is used, i.e., Mab or polyclonal, the amount of detectable expression for nmMHCA varies even for the single given MKN45 human gastric tumor. Further none of the antibodies shows an increased expression over 18 times the cultured cell amount when the GAH antibody was used. Thus the ranges for the production amount and the ranges for the cell-surface expression amount are not nearly supported for the breadth of gastric tumor cells much less for even the breast, colon and esophageal cancer cells as instantly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/75067 (HYSEQ, INC; published 10/11/2001; cited in the IDS of 12/21/05) as evidenced by Creighton et al. (Genome Biol. 4(7):R46 (2003)).

The interpretation of the claims is of record and discussed as herein. The claims are interpreted as the antigen comprising the non-muscle myosin heavy chain type 2.

WO 01/75067 A discloses the antigenic protein, NMMHC type 2, see SEQ ID NO: 32080 corresponding to SEQ ID NO:17, which is expressed in cancer cells such as breast cancer, gastrointestinal cancer, colon cancer and esophageal cancer (p. 55), and where the protein is antigenic. The NMMHC type 2 was well recognized as a tumor marker for some cancers, and as evidenced by Creighton, it was also well established in the field art that cultured cancer cells could be altered in their expression of certain genes because of the in vitro growth conditions, and that by being transplanted subcutaneously into mice, tumor growth is associated with up-regulation of gene expression. Thus it is not unexpected that by subcutaneous transplanting a cancer cell expressing NMMHC type 2 that the tumor cell expression of the protein could be upregulated in vivo.

Specifically, with respect to chemical compositions and properties, a long line of cases stands for the principal that the recitation of a new property of a known compound does not establish patentable novelty over the old compound. (*E.g., In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (CA FC 2004) ("the PTO's position that the discovery of new properties of a known material does not make claims reciting those properties novel is correct"); *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657

(Fed. Cir. 1990) ("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition ."); *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); *In re Benner*, 174 F.2d 938, 942, 82 USPQ 49, 53 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product"). Stated another way, a claim to a compound in which the sole "novelty" recited in the claim is a newly discovered property, the claim does not distinguish the claimed subject matter from the known compound for the purposes of anticipation. An example illustrates this point. Where the prior art discloses a specific compound X and that it is useful for treating certain heart conditions, a later claim to the same compound but reciting a new property, e.g., "Compound X that grows hair" is anticipated by the earlier disclosure of compound X, notwithstanding that the new property is newly discovered and unobvious. The reason it is unpatentable is that the substance, compound X, is the same. Only additional information about the old compound has been provided.)

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LAB

/David J Blanchard/
Primary Examiner, Art Unit 1643